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EXAMINER

HOFFA, ANGELA MARIE

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/598,004
Filing Date: May 10, 2007
Appellant(s): KOEHLER ET AL.

George Hoskins
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 15, 2010 appealing from the Office action mailed August 2, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:
Claims 1-10 and 12-20.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,397,098	Uber III et al ("Uber")	5-2002
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(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 8-9, 10, 12-14, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,397,098 to Uber.

Regarding Claim 1, Uber discloses a method of controlling a local application of drugs to a part of a body of a patient during a CT scan (col. 7, line 2), wherein the drugs are transported in containers suitable for introduction into a bloodstream of the patient (injection needle, fig. 1; molecules, col. 15, lines 1-10); wherein the containers prevent an application of the drugs (syringe/needle assembly, fig. 1; molecules are not activated to release drug initially, col. 15, lines 1-3); and wherein a first drug is transported in a first container (contrast agent, fig. 1; drug, col. 15, lines 1-2); the method comprising the steps of:

Monitoring a heart beat rate (col. 10, lines 29-31) of the patient during the CT scan (col. 7, line 2);

Rupturing the first container (injecting contrast with needle injector inserted into the blood stream; activating with x-ray to release drug, col. 15, lines 1-3) in proximity to the part of the body on the basis of the monitored heart beat rate (to increase or decrease perfusion, col. 14, lines 1-8), resulting in a local application of the first drug to the part of the body (col. 10, lines 29-31, controlled rate of contrast agent injection based on heart beat rate) and wherein the rupturing the first container results in a controlled change of the heart beat rate (activating with x-ray to release vasodilator/constrictor drugs to increase perfusion, col. 14, lines 5-8, col. 15, lines 1-3).

Regarding Claims 2 and 4, Uber further discloses wherein the drugs can be locally applied to the heart via rupturing the first container; and wherein the rupturing the first container results in a controlled change of the heart beat rate (activating with x-ray to release vasodilator/constrictor drugs to increase perfusion, col. 14, lines 5-8, col. 15, lines 1-3).

Regarding Claim 3, Uber further discloses wherein the containers can be activated via ultrasound (col. 15, lines 1-3).

Regarding Claim 7, Uber further discloses the use of microbubbles carrying drugs administered to increase and decrease cardiac output load (col. 10, lines 32-35).

The features of Claims 8-9, 10, 12-14, and 17-19 are disclosed in the rejection of claims 1-4 and 7 above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 6, 15, 16, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uber.

Regarding Claims 5-6, 15-16, and 20, Uber further suggests that microbubbles can be selectively ruptured based on their size but does not disclose carrying two types of drugs with two differently sized microbubbles. Uber further suggests that two types of drugs are applied to vary perfusion rates of the patient for a stress test (vasodilators/vasoconstrictors) which are known to have an effect on heart beat rate (col. 14, lines 1-8). Uber further discloses the use of microbubbles carrying drugs administered to increase and decrease cardiac output load (col. 10, lines 32-35).

Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to provide two differently sized microbubbles for drug delivery of vasodilators/vasoconstrictor drugs for varying heart rate during an imaged stress test as suggested by Uber.

(10) Response to Argument

Applicant argues that Uber does not anticipate Claim 1 because Uber does not disclose the limitation of controlling a change of the heart beat rate of the patient "to reduce variations in the heart beat rate during the CT scan". However, Uber discloses the administration of a drug to the patient, during the CT scan, to control the heart beat rate of the patient during a stress test (col. 10, lines 31-37). Uber specifically recites "Connected sensors for monitoring heart rate and blood pressure may be used to

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initiate, terminate or adjust the injection process when these parameters reach certain levels". As pointed out in the rejection above and the previously mailed office action, Uber controls the heart rate for a different purpose than Applicant's invention. Uber controls the heart rate for the purpose of a stress test while Applicant controls the heart rate to reduce variations in resulting images. Uber administers vasodilator and vasoconstrictor drugs to increase and decrease cardiac output load. Certain heart beat levels are desired to be maintained for a certain amount of time during a stress test; therefore, Uber is reducing variations in the heart beat rate for at least that certain amount of time. Since reducing variations in the heart beat rate inherently reduces variations in image distortions, *the method of Uber produces the same results as claimed by Applicant*, despite being for different intended purposes.

From the limitation of "to reduce variations in the heart beat rate during the CT scan", Applicant argues that a two-way result is claimed and Uber only teaches a one-way result. Applicant argues that Uber discloses a one-way driving mechanism for achieving a target heart rate; that is, Uber either drives the heart rate one way to achieve a target level. Although Uber does not disclose the specific timing of when to increase or decrease the heart rate, *Uber does disclose a **two-way driving mechanism to change** the heart rate to reach a target level during a stress test and suggests a **one-way drug-controlled driving mechanism to maintain** the heart rate at the target level* (vasodilator and vasoconstrictor drugs, which either increase and decrease cardiac output). For example, in the case of a stress test, if the patient is given the drug to speed up his heart, his heart will naturally try to slow down to a normal

pace as the drug wears off. An additional drug to slow his heart down would not be needed to maintain the heart beat at the relatively fast pace – this represents a one-way driving mechanism from the drug in a naturally two-way driving mechanism process to maintain the heart beat rate. Similarly, the patient being given a drug to slow his heart would be the same in reverse – a one-way drug-controlled process in the opposite direction. Uber discloses the two directions (speed up or slow down) and therefore discloses a two-way process to achieve the desired heart beat rate. The naturally-occurring two-way process suggested by Uber may also be considered a two-way process. Applicant discloses ***a two-way driving mechanism to maintain the heart rate at **only one** given level.*** However, this difference is not clarified in the claimed subject matter. Given its broadest reasonable interpretation, the result of “reducing variations” would not necessarily be a two-way result since a change in one direction can lead to a steady heart beat rate, thereby reducing variations. Even if this limitation was interpreted as a two-way result, Uber still reads on a two-way process for the reasons above.

Applicant further argues with respect to the 103 rejection of claims 5, 15, and 20, that Uber does not provide evidence for a case of obviousness of the feature of using two types of drugs at the same time. Applicant contends that since using one or the other of the two drugs is sufficient to achieve the goals of Uber, it would not be obvious to use both kinds of drugs during an imaging scan. Claims 5, 15, and 20 include a second drug in a second container but are silent with respect to the purpose of the second drug application. Claims 6 and 16 then claim that the second drug is for

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decreasing the heart rate and the first drug is for increasing the heart rate. Uber provides evidence for using different drugs to either increase or decrease the heart rate in a cardiac stress test. Since no language in the claims provides for using the two different drugs to achieve the same target heart rate, the claim is broad enough in scope to include the drug application for the cardiac stress test of Uber (i.e. applying the first drug to speed up the heart to a first desired rate, applying the second drug to slow down the heart to a second desired rate). While it is agreed that Uber does not provide evidence or suggestion for using two types of drugs to achieve and maintain the same target heart beat rate, the claim does not require this feature.

The above differences between Uber and Applicant's invention were discussed in the interview held Oct. 6, 2010 and allowable subject matter has been identified in a prior action. In the appeal brief, Applicant recites the portion of the office action where the allowable subject matter had been indicated. The allowable subject matter indication has not been withdrawn by the examiner. The indication was *not* placed in the action as a suggestive wording for the claim, but as merely a reference to the subject matter that if positively incorporated into the claim would put the application into conditions for allowance. Rather than relying on functional language to claim the invention, the examiner asked Applicant to consider language that would positively define the steps of the method to include the allowable subject matter. However, Applicant would not consider claim amendments to clarify the invention over Uber in this manner and an agreement could not be reached.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Angela M. Hoffa/

Examiner, Art Unit 3768

Conferees:

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768

/Thomas J Sweet/

Supervisory Patent Examiner, Art Unit 3779